

K960055

SEP 30 1996

**PREMARKET APPROVAL NOTIFICATION CERTIFICATION AND SUMMARY**

(To be submitted when claiming equivalence to a Class III device)

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the BioGlide Vascular Catheter, single lumen. I further certify that I am aware of the types of problems to which the BioGlide Vascular Catheter, single lumen is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the BioGlide Vascular Catheter, single lumen is complete and accurate.

Complications associated with the use of the device may be similar to those experienced in any other surgical procedure carried out under local and/or general anesthetic:

Reactions to drugs or anesthetic agents;  
Electrolyte imbalance;  
Excessive Blood loss;

Local and Systemic Infections are not uncommon with this type of procedure. They are most usually due to organisms that inhabit the skin, particularly *Staphylococcus epidermidis*. However, other pathogens circulating in the blood stream may colonize the device and in the majority of patients require its removal.

Other potential complications are listed:

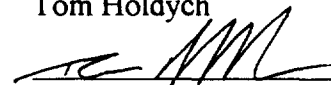
Catheter or cuff erosion through skin	Endocarditis
Catheter malposition, occlusion, fibrin sheath formation at tip, dislodgment, or rupture	Cardiac arrhythmia
Intolerance reaction to implanted device	Thrombophlebitis
Vascular thrombosis	Sepsis or infection
Perforation or laceration of vessels or viscous	Embolus
Pneumothorax, hemothorax, or hydrothorax	Brachial plexus injury
Postural related catheter occlusion, damage, or breakage due to catheter crimping between the clavicle and first rib	Hematoma
	Cardiac tamponade
	Exit site necrosis

A Bibliography or other citation of the materials upon which the above summary is based is found in Attachment 7 of this submission.

Printed name of person required to submit 510(k):

Tom Holdych

Signature of person required to submit 510(k):



Title of person submitting 510(k):

Director Regulatory Affairs and Quality Assurance

Name of Company:

Medtronic PS Medical Corporation

Date:

1/3/96